

**K920616 DIASTAT ANTI-HISTONE KIT**Jul 14, 1992  
154 days to decisionK920616 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k920616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Feb 11, 1992
Decision date	Jul 14, 1992
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shield Diagnostics, Ltd.</b>
Location	Scotland, KN
Contact	GEORGE ZAJICEK
510(k) history	27 submissions · 27 cleared · 1990-2000

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